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| EXAMINER | |
|---|---|
| ROZANSKI, MICHAEL T | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/723,847 | CHIN ET AL. | |
| | Examiner | Art Unit | |
| | Michael Rozanski | 3768 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that none of the cited references disclose a patient leg with length indications or a computer system that receives information regarding the depth of insertion. Examiner respectfully disagrees and finds that Tearney et al. describe a gearing mechanism made to allow a motor to axially drive the entire endoscopic imaging unit (and optical fiber) in the axial direction, thus creating three dimensional maps of the sample of interest (col. 10, lines 62-67). In addition, Woker et al. teach of indicia on the inner catheter and the instrument to indicate at least one longitudinal position of the instrument relative to the distal end of the everting element (col. 2, lines 3-6). Further, the markings may be provided in any form which is human or machine readable (col. 2, lines 42-44). In general, "machine readable" may be interpreted to include a sensor that is connected to a computer system.

It would have been obvious to use the combination of Tearney et al, Bowker, and Woker. In specific response to the arguments, Examiner asserts that modifying Tearney et al in view of Woker is obvious because Woker is used to teach length indicia indicating a depth of insertion of a leg into a body cavity. While Tearney et al disclose longitudinal scanning accomplished by changing the length of the reference arm rather than the measuring arm, it is also disclosed that the endoscopic unit (i.e. measuring arm) is inserted axially (col. 10, lines 62-67). In one respect, it would have been

obvious to put indicia on the measuring arm of Tearney et al because it does move axially and knowing the depth of insertion would be useful to generate 3D maps of the body cavity.

In addition, the amended claims have overcome the claim objections, which is now withdrawn. For the reasons given in this response and below, this office action is made FINAL because the claims have been amended, but arguments are not persuasive. Newly added claims 12-14 are also rejected for similar reasons.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. ***Claims 1-14*** are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Tearney et al*** (US 6,134,003) in view of ***Bowker*** (US 3,597,091), and further in view of ***Woker et al*** (US 5,163,927).

In reference to claim 1, Tearney et al. disclose an imaging system comprising an endoscopic unit and an interferometer for performing multi-dimensional scanning of a structure by utilizing an optical coherence tomography technique (col. 2, lines 5-7). Although the term endoscope is used when describing the capabilities of the Tearney et al. imaging system, it is noted that the invention directly relates to guidewires, catheters, and imaging with probes placed through trocars (col. 3, lines 20-22). Therefore, the

system is capable of measuring dimensions of a body cavity. The imaging system includes an optical radiation source 2, a measuring arm 10 including an endoscopic unit 34 for being insertable into a patient's body, a reference arm 8 including a reference reflector 12 at an end thereof, and a beam divider 6 which divides light from the light source into paths defining a measuring arm and a reference arm and combines reflected radiation from the reference reflector and the structure 14 (col. 4, lines 26-29 & 44-46). As shown in Figure 4, the measuring arm 110 includes the optical fiber 32, which is capable of directing light from the source against a wall of the body cavity and receiving reflected light, and the reference arm 188 including the optical fiber 22. Figure 15 shows two detectors 417, 415 positioned in quadrature that serve to generate electrical signals representative of the interference pattern (i.e. fringes) of the combined light. The detectors transmit signals to a processing unit 418 that includes signal processing and control electronics. The magnitude of the interference pattern (i.e. fringes) is proportional to the structure's reflection coefficient the frequency of which is proportional to the differential optical path length (col. 19, lines 5-8).

Tearney et al. do not, however, specifically disclose a source of coherent light or a processor that counts fringes. In the same field of endeavor, Bowker teaches of an interferometer distance-measuring engine. The interferometer utilizes a laser light beam to provide a coherent source of light (col. 4, lines 67-68). Referring to Figure 4, one detector is in phase quadrature with a second detector, both of which are coupled to a fringe counter 69 to provide an indication of the degree and direction of displacement (col. 10, lines 71-75). Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to incorporate a coherent light source and a fringe counter, wherein the number of fringes is proportional to the distance between an end of the optical fiber of the measuring arm and the wall of the body cavity. Coherent light is utilized in order to permit interference in regard to light waves.

Tearney et al also do not disclose a catheter that includes length indications or a computer that receives depth information. In the same field of endeavor, Woker et al. teach of indicia on the inner catheter and the instrument to indicate at least one longitudinal position of the instrument relative to the distal end of the everting element (col. 2, lines 3-6). Further, the markings may be provided in any form which is human or machine readable (col. 2, lines 42-44). In general, "machine readable" may be interpreted to include a sensor that is connected to a computer system. Tearney et al. describe a gearing mechanism made to allow a motor to axially drive the entire endoscopic imaging unit (and optical fiber) in the axial direction, thus creating three dimensional maps of the sample of interest (col. 10, lines 62-67). The imaging information from the endoscopic unit is transmitted to the signal processing, electronics control, and display unit to construct a model of the body cavity (see Fig. 1). This unit 18 functions as a computer system. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Woker et al. to have a catheter with length indicia and a computer system that receives information regarding a depth of insertion of the catheter in order to construct a model of the body cavity.

In reference to claim 2, Bowker does not disclose a mechanism for rotating light emitted from optical fibers in the patient leg in the body cavity. However, Tearney et al. describes a rotational scanning mechanism 35 that causes rotation of the optical fiber 44 of the endoscopic unit 34 in the measuring arm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a system further comprising a mechanism for rotating the light emitted by the optical fiber in the measuring arm within the body cavity. This enables a circumferential scan of a body cavity improved diagnosis procedures.

In reference to claim 3, Bowker does not disclose a mechanism for rotating the light including a rotatable optical coupler. However, Tearney et al. teaches of the rotational scanning mechanism 35 typically including a rotation mechanism 52 and an optical coupling system 53 (see Fig. 8). The coupling system 53 includes a coupling member 70 that is spaced by an interface 72 from an optical connector 48 affixed to the proximal end of the endoscopic unit 34. The interface 72 serves to transmit optical radiation from the input optical fiber 32 to the optical fiber 44 of the endoscopic unit (col. 9, lines 25-35). Upon activation of the drive motor 74, the shaft 78 rotates causing the rotatable optical fiber 44 to rotate (col. 9, lines 55-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a rotatable optical coupler for coupling light to the optical fiber and a motor for rotating the optical fiber. This improves the circumferential scanning of a body cavity by incorporating a more stable rotating mechanism.

In reference to claim 4, Bowker does not disclose optical fibers routed in a catheter or a mechanism for rotating the catheter. However, Tearney et al. teach of the endoscopic unit 34 coupled to a rotational scanning mechanism 35. Tearney et al. notes that although the term endoscope is used, the invention directly relates to catheters (col. 3, lines 19-21). Since the mechanism 35 is coupled to the endoscopic unit 34, then the endoscope will rotate along with the optical fiber 44 (see Fig. 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a mechanism for rotating a catheter with an optical fibers routed therein. This helps in transmitting and receiving the interferometric signal while within a body cavity.

In reference to claim 5, Bowker does not disclose a movable light deflector for directing emitted light in the body cavity. However, Tearney et al. describe a beam director that controls the focusing parameters of the optical beam. Further, the beam director is located on the distal end 47 of the endoscopic unit 34. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a movable light deflector, or beam director, at the distal end of the measuring arm to direct light in the cavity. This enables one to change the direction of the emitted light without removing the endoscope.

In reference to claims 6, 7, 8, and 10, Tearney et al. in view of Bowker do not disclose a catheter that includes length indications or a computer that receives depth information. Woker et al. teach of indicia on the inner catheter and the instrument to indicate at least one longitudinal position of the instrument relative to the distal end of

the everting element (col. 2, lines 3-6). Further, the markings may be provided in any form which is human or machine readable (col. 2, lines 42-44). In general, "machine readable" may be interpreted to include a sensor that is connected to a computer system. Tearney et al. describe a gearing mechanism made to allow a motor to axially drive the entire endoscopic imaging unit (and optical fiber) in the axial direction, thus creating three dimensional maps of the sample of interest (col. 10, lines 62-67). The imaging information from the endoscopic unit is transmitted to the signal processing, electronics control, and display unit to construct a model of the body cavity (see Fig. 1). This unit 18 functions as a computer system. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Woker et al. to have a catheter with length indicia and a computer system that receives information regarding a depth of insertion of the catheter in order to construct a model of the body cavity.

In reference to claim 9, Tearney et al. disclose an endoscopic imaging system that is capable of measuring an internal body cavity of a patient. The system utilizes an interferometer 4 that directs a beam of light into a reference arm 8 and a measuring arm 10 that is insertable into the body cavity. A rotational scanning mechanism 35 is coupled to the endoscopic unit 34 and causes rotation of the optical fiber 44. This mechanism rotates the beam of light in the measuring arm within the body cavity and receives light via that is reflected from a wall of the body cavity via the optical fiber. The system also includes a detector 16 that detects the interference pattern and generates electrical signals representative of the combined radiation from the reference and

measuring arms (col. 4, lines 47-52). The detector, therefore, is capable of detecting the difference in optical path length between the light directed into the measuring and reference arms. Tearney et al. further describe a gearing mechanism made to allow a motor to axially drive the entire endoscopic imaging unit (and optical fiber) in the axial direction, thus creating three dimensional maps of the sample of interest (col. 10, lines 62-67). The imaging information from the endoscopic unit is detected by the detector and then transmitted to the signal processing, electronics control, and display unit to construct a model of the body cavity (see Fig. 1). This unit 18 functions as a computer system.

Tearney et al., however, do not specifically disclose a coherent light source or a patient leg with a marking indicating the depth of insertion. In the same field of endeavor, Woker et al. teach of indicia on a catheter to indicate longitudinal position of the instrument (col. 2, lines 3-5). The indicia may be provided in any form which is either human or machine readable (col. 2, lines 42-44). Also in the same field of endeavor, Bowker teaches of a laser light beam that provides a coherent source of light (col. 4, lines 67-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teaches of Woker et al. and Bowker to have a system comprising an interferometer utilizing a coherent light source and a marking on the patient leg to indicate depth of insertion, a rotating mechanism, a detector to detect the optical path length difference, a computer system that receives signals from the detector, and an indication of the depth of insertion in order to construct a three-dimensional model of the body cavity.

In reference claim 11, Woker et al. do not disclose a detector including a first and second sensor positioned in quadrature. However, attention is drawn to both Tearney et al. and Bowker. Tearney et al. teach of a receiver 416 that employs two detectors 417, 415. In this case, the receiver may function as a detector unit that includes the detectors, which may function as a first and second sensor positioned in quadrature (see Fig. 15). Similarly, Bowker teaches of two detectors leading to a pair of photomultiplier tubes 65, 66 with one in phase quadrature with the other (see Fig. 4). In this case, the photomultipliers are rigidly coupled together along with other elements (col. 11, lines 16-19). Thus, the system could be described as comprising a detector unit including two photomultipliers that function as sensors positioned in quadrature. Tearney et al. describes a gearing mechanism made to allow a motor to axially drive the entire endoscopic imaging unit (and optical fiber) in the axial direction, thus creating three dimensional maps of the sample of interest (col. 10, lines 62-67). The imaging information from the endoscopic unit is transmitted to the signal processing, electronics control, and display unit to construct a model of the body cavity (see Fig. 1). This unit 18 functions as a computer system. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a detector that includes a first and second sensor positioned in quadrature for detecting the signals. This improves the detection of the interferometric signal by comparing the differences between the two signals.

## *Conclusion*

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show interferometric systems and catheter markers.

US Patent No. 6,384,915 to Everett et al. which disclose an optic coupler 14, reference arm 18, reference mirror 26, sample arm 42, optical fibers, and balanced detectors for measuring body cavities.

US Patent No. 5,218,419 to Lipson et al. which disclose a fiberoptic interferometric sensor system 10 with a reference fiber 26 and a sensing fiber 24.

US Patent No. 6,036,682 to Lange et al., which disclose a catheter 30 with radiopaque segments that serve as marker bands and are visible under fluoroscopy.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR
MR

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